

#10
3-11-02
P.2.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Winfried Edelmann *et al.*

Serial No.: 09/658,969

Filed: September 11, 2000

For: *METHODS FOR MODULATING THE
ACTIVITY OF MSH5 (as Amended)*

Attorney Docket No.: AHN-001DV2

Group Art Unit: 1632

Examiner: Peter Paras, Jr.

RECEIVED

MAR - 6 2002

TECH CENTER 1600/2900

COPY OF PAPERS
ORIGINALLY FILED

Commissioner for Patents
Washington, D.C. 20231

Certificate of First Class Mailing (37 CFR §1.8(a))

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, Washington, D.C. 20231 on the date set forth below.

January 31, 2002
Date of Signature and of Mail Deposit

By: *Maria C. Laccotripe*
Maria c. Laccotripe, Ph.D.
Limited Recognition Under 37 C.F.R. §10.9(t)
Attorney for Applicants

RESPONSE TO RESTRICTION REQUIREMENT

Dear Sir:

This is in response to the restriction requirement set forth in the Office Action dated December 4, 2001 (Paper No. 8). A separate petition for the appropriate extension of time in which to respond is being filed concurrently herewith.

The Examiner has required restriction to one of the following inventions under 35 U.S.C. §121:

- I. Claims 15-17, 22, and 30 drawn to an *in vitro* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein the activity of MSH5 is inhibited, and wherein said compound is a contraceptive, classified in class 435, subclass 4.

II. Claims 15-17, 23-24, and 30 drawn to an *in vitro* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein the compound can modulate expression of MSH5, and wherein said compound is an antisense MSH5 nucleic acid molecule, classified in class 536, subclass 24.5.

III. Claims 15, 25, and 30 drawn to an *in vitro* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein said compound is a small molecule, classified in class 436, subclass 501.

IV. Claims 15, 26, and 30 drawn to an *in vitro* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein said compound is an antibody, classified in classes 435, and 530 subclasses 7.1, and 387.1.

V. Claims 15, 27, and 30 drawn to an *in vitro* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein said compound is a peptide, classified in class 435, subclass 7.2.

VI. Claims 15, 28, and 30 drawn to an *in vitro* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein said compound is a peptidomimetic, classified in class 424, subclass 184.1.

VII. Claims 15 and 29-30, drawn to an *in vitro* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein said compound is has an effect on an MSH5 substrate, classified in class 435, subclass 6.

VIII. Claims 15-17, 22, and 31 drawn to an *in vivo* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein the activity of MSH5 is inhibited, and wherein said compound is a contraceptive, classified in class 435, subclass 4.

IX. Claims 15-17, 23-24, and 31 drawn to an *in vivo* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein the compound can modulate expression of MSH5, and wherein said compound is an antisense MSH5 nucleic acid molecule, classified in classes 536 and 514, subclasses 24.5 and 44.

X. Claims 15, 25, and 31 drawn to an *in vivo* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein said compound is a small molecule, classified in class 436, subclass 501.

XI. Claims 15, 26, and 31 drawn to an *in vivo* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein said compound is an antibody, classified in classes 435, 424, and 530 subclasses 7.1, 130.1 and 387.1.

XII. Claims 15, 27, and 31 drawn to an *in vivo* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein said compound is a peptide, classified in classes 424 and 435, subclasses 185.1 and 7.2.

XIII. Claims 15, 28, and 31 drawn to an *in vivo* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein said compound is a peptidomimetic, classified in class 424, subclass 184.1.

XIV. Claims 15 and 29-31, drawn to an *in vivo* method for modulating MSH5 expression or activity comprising contacting MSH% or a cell expressing MSH5 with a compound, wherein said compound is has an effect on an MSH5 substrate, classified in classes 514, 424, and 435, subclasses 44, 184.1, and 6.

Applicants hereby elect the Group VIII invention (claims 15-17, 22, and 31) drawn to an *in vivo* method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound, wherein the activity of MSH5 is inhibited, and wherein said compound is a contraceptive, for prosecution in this application, *with traverse*.

Applicants hereby *traverse* the foregoing Restriction Requirement on the grounds that Groups I-XIV should be re-grouped as a single invention, as Groups I- XIV encompass inventions which are connected in design, operation, and effect, *i.e.*, are not independent (M.P.E.P. §808.01). Applicants have presented generic claim 15 which is directed to a method for modulating MSH5 expression or activity comprising contacting MSH5 or a cell expressing MSH5 with a compound in a sufficient concentration to modulate MSH5 expression or activity. The *compound that modulates MSH5 expression or activity* can be a small molecule, a polypeptide, a peptidomimetic, an antisense nucleic acid molecule, or an anti-MSH5 antibody. These compounds have the same effect, *i.e.*, they modulate MSH5 activity, and the same design and operation. For example, a peptide, a peptidomimetic and an antibody operate by binding to an active site on the MSH5 polypeptide, thereby modulating its activity.

For the foregoing reasons, Applicants respectfully submit that a sufficient search and examination with respect to the inventions of Groups I-XIV can be made without serious burden on the Examiner. As the M.P.E.P. states:

[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions.

M.P.E.P. § 803.

The inventions of Groups I, IV, V, VI, VIII, XI, XII and XIV have all been classified in Class 435. As such, the searches with regard to these inventions would be co-extensive and would not involve a serious burden on the Examiner. For example, the contraceptive of Groups I and VIII could be a small molecule (now classified in Groups III and X), an antibody (now classified in Groups IV and XI), a peptide (now classified in Groups V and XII), or a peptidomimetic (now classified in Groups VI and XIII).

Finally, Applicants respectfully traverse the Examiner's requirement that *in vitro* and *in vivo* applications be restricted to separate Groups. Applicants respectfully submit that these inventions are not independent and distinct in that they are connected in design, operation and effect. Both methods use the same starting material, which operates in the same manner to achieve the same effect: modulation of MSH5 activity.

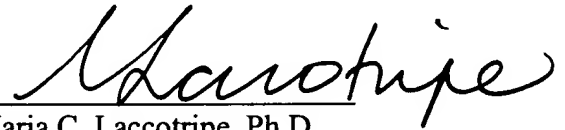
Applicants believe that a *species election*, e.g., wherein the compound is a small molecule, may be proper for searching purposes only, posing no undue burden on the Examiner. However, a restriction under 35 U.S.C. § 121 is improper for above-stated reasons. Accordingly, Applicants hereby request that the invention of Groups I-XIV be combined into a single Group.

Applicants reserve the right to traverse the restriction between the non-elected groups in this or a separate application.

SUMMARY

If a telephone conversation with Applicants' Attorney would expedite the prosecution of the above-identified application, the Examiner is urged to call Applicants' Attorney at (617) 227-7400.

Respectfully submitted,



Maria C. Laccotripe, Ph.D.

Attorney for Applicants

Limited Recognition Under 37 C.F.R. §10.9(b)

LAHIVE & COCKFIELD, LLP
28 State Street
Boston, MA 02109
Tel. (617) 227-7400

Dated: January 31, 2002